Assessment of listing and categorisation of animal diseases within the framework of the Animal Health Law (Regulation (EU) No 2016/429): Koi herpes virus disease (KHV)

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2017-06-21

Depner , K & Panel on Animal Health and Welfare (AHAW) 2017 , ' Assessment of listing and categorisation of animal diseases within the framework of the Animal Health Law (Regulation (EU) No 2016/429): Koi herpes virus disease (KHV) ' , EFSA Journal , vol. 15 , no. 7 , 4907 . https://doi.org/10.2903/j.efsa.2017.4907

http://hdl.handle.net/10138/231217
https://doi.org/10.2903/j.efsa.2017.4907

SCIENTIFIC OPINION

EFSA Journal

ADOPTED: 18 June 2017

doi: 10.2903/j.efsa.2017.4907

Assessment of listing and categorisation of animal diseases within the framework of the Animal Health Law (Regulation (EU) No 2016/429): Koi herpes virus disease (KHV)

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Abstract

Koi herpes virus (KHV) disease has been assessed according to the criteria of the Animal Health Law (AHL), in particular criteria of Article 7 on disease profile and impacts, Article 5 on the eligibility of KHV disease to be listed, Article 9 for the categorisation of KHV disease according to disease prevention and control rules as in Annex IV and Article 8 on the list of animal species related to KHV disease. The assessment has been performed following a methodology composed of information collection and compilation, expert judgement on each criterion at individual and, if no consensus was reached before, also at collective level. The output is composed of the categorical answer, and for the questions where no consensus was reached, the different supporting views are reported. Details on the methodology used for this assessment are explained in a separate opinion. According to the assessment performed, it is inconclusive whether KHV disease can be considered eligible to be listed for Union intervention as laid down in Article 5(3) of the AHL because there was no full consensus on the criterion 5 A(v). Consequently, the assessment on compliance of KHV disease with the criteria as in Annex IV of the AHL, for the application of the disease prevention and control rules referred to in Article 9(1) is also inconclusive, as well as which animal species can be considered to be listed for KHV disease according to Article 8(3) of the AHL.

Keywords: Koi herpes virus disease, KHV, Animal Health Law, listing, categorisation, impact

Requestor: European Commission

Question number: EFSA-Q-2016-00589

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Acknowledgements: The Panel wishes to thank Nick Taylor for the support provided to this scientific output.

Suggested citation: EFSA AHAW Panel (EFSA Panel on Animal Health and Welfare), More S, Bøtner A, Butterworth A, Calistri P, Depner K, Edwards S, Garin-Bastuji B, Good M, Gortázar Schmidt C, Michel V, Miranda MA, Nielsen SS, Raj M, Sihvonen L, Spoolder H, Stegeman JA, Thulke H-H, Velarde A, Willeberg P, Winckler C, Baldinelli F, Broglia A, Zancanaro G, Beltrán Beck B, Kohnle L, Morgado J and Bicout D, 2017. Scientific Opinion on the assessment of listing and categorisation of animal diseases within the framework of the Animal Health Law (Regulation (EU) No 2016/429): Koi herpes virus disease (KHV). EFSA Journal 2017;15(7):4907, 35 pp. https://doi.org/10.2903/j.efsa.2017.4907

ISSN: 1831-4732

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1. Introduction

1.1. Background and Terms of Reference as provided by the requestor

The background and Terms of Reference (ToR) as provided by the European Commission for the present document are reported in section 1.2 of the scientific opinion on the ad hoc methodology followed for the assessment of the disease to be listed and categorised according to the criteria of Article 5, Annex IV according to Article 9, and 8 within the Animal Health Law (AHL) framework (EFSA AHAW Panel, 2017).

1.2. Interpretation of the Terms of Reference

The interpretation of the ToR is as in section 1.2 of the scientific opinion on the ad hoc methodology followed for the assessment of the disease to be listed and categorised according to the criteria of Article 5, Annex IV according to Article 9, and 8 within the Animal Health Law (AHL) framework (EFSA AHAW Panel, 2017).

The present document reports the results of assessment on Koi herpes virus (KHV) disease according to the criteria of the AHL articles as follows:

- Article 7: Koi herpes virus (KHV) disease profile and impacts
- Article 5: eligibility of Koi herpes virus (KHV) disease to be listed
- Article 9: categorisation of Koi herpes virus (KHV) disease according to disease prevention and control rules as in Annex IV
- Article 8: list of animal species related to Koi herpes virus (KHV) disease.

2. Data and methodologies

The methodology applied in this opinion is described in detail in a dedicated document about the ad hoc method developed for assessing any animal disease for the listing and categorisation of diseases within the AHL framework (EFSA AHAW Panel, 2017).

3. Assessment

3.1. Assessment according to Article 7 criteria

This section presents the assessment of KHV disease according to the Article 7 criteria of the AHL and related parameters [see Table 2 of the opinion on methodology (EFSA AHAW Panel, 2017)], based on the information contained in the fact-sheet as drafted by the selected disease scientist (see section 2.1 of the scientific opinion on the ad hoc methodology) and amended by the AHAW Panel.

3.1.1. Article 7(a) Disease Profile

3.1.1.1. Article 7(a)(i) Animal species concerned by the disease

Susceptible animal species

Parameter 1 – Naturally susceptible wildlife species (or family/orders)

Koi herpes virus disease (KHVD) is caused by Cyprinid Herpes Virus-3 (CyHV-3) which is otherwise known as Koi herpes virus (KHV). This is a DNA virus from the Alloherpesvirus family which predominantly affects common carp (*Cyprinus carpio*, family: Cyprinidae, order: Cypriniformes) and its varieties (OIE, online).

Parameter 2 – Naturally susceptible domestic species (or family/orders)

Common carp (*Cyprinus carpio*, family: Cyprinidae, order: Cypriniformes) and its varieties (OIE, online).

Parameter 3 – Experimentally susceptible wildlife species (or family/orders)

Common carp (*Cyprinus carpio*, family: Cyprinidae, order: Cypriniformes) and its varieties. Mortality also observed in hybrids of carp × goldfish (*Carassius auratus*, family: Cyprinidae, order: Cypriniformes) and carp × crucian carp (*Carassius carassius*, family: Cyprinidae, order: Cypriniformes) (Hedrick et al., 2006; Bergmann et al., 2010b).

Parameter 4 – Experimentally susceptible domestic species (or family/orders)

Common carp (*Cyprinus carpio*, family: Cyprinidae, order: Cypriniformes) and its varieties. Mortality also observed in hybrids of carp × goldfish (*Carassius auratus*, family: Cyprinidae, order: Cypriniformes) and carp × crucian carp (*Carassius carassius*, family: Cyprinidae, order: Cypriniformes) (Hedrick et al., 2006; Bergmann et al., 2010b).

Reservoir animal species

Parameter 5 – Wild reservoir species (or family/orders)

KHV nucleic acids have been detected by polymerase chain reaction (PCR) in freshwater mussels and crustacea. Cohabitation experiments suggest asymptomatic infection of goldfish, tench (*Tinca tinca*), vimba (*Vimba* spp.), common bream (*Abramis brama*), common roach (*Rutilus rutilus*), European perch (*Perca fluviatilis*), ruffe (*Gymnocephalus cernua*), gudgeon (Gobioninae), rudd (*Scardinius erythrophthalmus*), northern pike (*Esox Lucius*), Prussian carp (*Carassius gibelio*), silver carp (*Hypophthalmichthys molitrix*) and grass carp (*Ctenopharyngodon idella*) that can subsequently transmit to naïve carp (El-Matbouli et al., 2007; Kempter and Bergmann, 2007; Kempter et al., 2009; Kielpinski et al., 2010; El-Matbouli and Soliman, 2011; Kempter et al., 2012; Fabian et al., 2013; Radosavljevic et al., 2012). The World Organization for Animal Health (OIE, online) also lists goldfish, grass carp, ide (*Leuciscus idus*), catfish, Russian sturgeon (*Acipenser gueldenstaedtii*) and Atlantic sturgeon (*Acipenser oxyrinchus*) as carrier species.

Parameter 6 – Domestic reservoir species (or family/orders)

Goldfish (*Carassius auratus*, family: Cyprinidae, order: Cypriniformes) (Bergmann et al., 2010a).

3.1.1.2. Article 7(a)(ii) The morbidity and mortality rates of the disease in animal populations

Morbidity

Parameter 1 – Prevalence/incidence

Limited information is available, and there is a knowledge gap in terms of acquiring this information at the national level. Some case study based data has been reported from a variety of countries. A serological survey by Taylor et al. (2010a) suggests that in the UK between 85% and 93% of the population in lakes with clinically affected carps tested positive for KHV antibodies (Taylor et al., 2010a). In lakes and farms where no clinical disease has been observed seroprevalences ranged between 5% and 25% (mean = 14.75%, median = 14%). In lake Biwa, Japan, 54% of the carp population tested antibody positive for KHV after a disease outbreak in 2006 (Uchii et al., 2009).

Parameter 2 – Case-morbidity rate (% clinically diseased animals out of infected ones)

With respect to prevalence and mortality, there are also knowledge gaps at the national level, with little data available to determine morbidity in farms or lakes across the European Union (EU). However, 100% morbidity has been observed in experimental studies on carp (Haenen et al., 2004; Bergmann et al., 2010b).

Mortality

Parameter 3 – Case-fatality rate

In experimental studies on carp, 70–80% mortality has been observed (Haenen et al., 2004; Bergmann et al., 2010b). However, in the case of natural infections, there is a knowledge gap relating to observed mortality rates. Several studies suggest that mortality due to KHV (in lake and farm systems) can be high. However, no reliable estimates of mortality rates are available in outbreak sites in Europe and elsewhere, due to difficulties in determining the total host population size. In Taiwan, data from cultured carp outbreaks showed mortality of 70–100% (Chen et al., 2015). Data on cases in UK lakes supplied by the Centre for Environment, Fisheries and Aquaculture Science (Taylor, 2016) show total mortalities occurred when water temperatures were in excess of 16°C, and were highly variable between sites (ranging between 1 and > 2,000 in number). Percentage values associated with these numbers are highly speculative, although thought to be around 10–20% on average; they could be as high as 90% in exceptional circumstances. The duration over which mortality is observed is also variable, but generally mortalities occur over a period of 12–20 days and is likely to be determined by

the transmission dynamics occurring within a population and temperature. Gilad et al. (2004) showed mortality to occur 5–8 days post-infection at 23–28°C, and Yuasa et al. (2008) showed mortality to occur at 14–21 days post-infection at 16–18°C (Gilad et al., 2003; Yuasa et al., 2008). Omori and Adams (2011) suggest that if infection occurs and the water temperature is subsequently reduced to below 16°C the mortality rates are likely to be low. Seasonality in water temperatures is therefore likely to be important in determining the level of mortality observed and the impact of the pathogen.

3.1.1.3. Article 7(a)(iii) The zoonotic character of the disease

No cases of KHV in humans have been reported.

3.1.1.4. Article 7(a)(iv) The resistance to treatments, including antimicrobial resistance

Parameter 1 – Resistant strain to any treatment even at laboratory level

At present, no treatments are available for KHV.

3.1.1.5. Article 7(a)(v) The persistence of the disease in an animal population or the environment

Animal population

Parameter 1 – Duration of infectious period in animals

A knowledge gap exists as little published information is available relating to the duration of virus shedding by infected fish. Yuasa et al. (2008) conducted studies by infecting fish with KHV and mixing them with naïve fish at different times post-infection. This study showed that fish could transmit the virus at 34, 14 and 12 days' post-exposure at 16, 23 and 28°C, respectively. Additionally, unpublished studies by the UK's Cefas suggest that fish exposed to KHV via bath challenge and then held individually at 20°C begin shedding the virus between 1 and 4 days post-exposure, and, if they survive infection can go on to shed virus up to day 25 post-exposure. However, in these experiments, 75% of fish died and the 50% survival time was day 13 post-exposure.

Parameter 2 – Presence and duration of latent infection period

The experimental studies described in the above section suggest that no significant latent period is observed in exposed fish prior to shedding, with virus being detected in fish mucous (i.e. shed) between 1 and 4 days post-exposure. Further research is required to confirm this and address the knowledge gap.

Parameter 3 – Presence and duration of the pathogen in healthy carriers

Though a true latent period prior to shedding has not been proven and demonstrates a knowledge gap requiring further study, long-term persistent infections have been demonstrated, and in common with other herpes viruses, it seems likely that latency does occur. Serological testing of fish in lakes that experienced clinical infections of KHV, show that seropositive fish could be detected 9 years post-outbreak. Although the research did not demonstrate presence of the pathogen, this duration of antibody persistence may suggest continued low level exposure to the virus and therefore persistence. This is supported by published experimental studies that detected low levels of KHV DNA up to 2 months post-infection in the gills, kidneys and brain of fish that survived primary infection and no longer showed clinical signs (Gilad et al., 2004). Other studies also confirmed the presence of KHV DNA in the brain of fish for as long as one year post-infection (Yuasa et al., 2012; Miwa et al., 2015). In wild populations, Uchii et al. (2009) were able to detect KHV DNA in the brain of both seropositive and negative carp for over 2 years post-outbreak. Reactivation of the virus in persistently infected fish had been demonstrated after moving fish between sites and the application of temperature stress several months after exposure to the virus (St-Hilaire et al., 2005; Bergmann and Kempter, 2011; Baumer et al., 2013). There is a knowledge gap surrounding other factors that may induce recrudescence of the virus in latently infected fish.

Environment

Parameter 4 – Length of survival (dpi) of the agent and/or detection of DNA in selected matrices (soil, water, air) from the environment (scenarios: high and low T)

KHV remains infectious in water for > 4 h, but < 21 h, at water temperatures of 23–25°C (Perelberg et al., 2003). Other studies in Japan have displayed a significant reduction in the infectious titre of KHV within 3 days in environmental water or sediment samples at 15°C, while the infectivity remained for more than 7 days when KHV was exposed to sterilised water samples (Shimizu et al., 2006).

In Japan, KHV DNA was detected in river water samples at temperatures of 9–11°C, 4 months prior to a KHV disease outbreak being observed in a river (Haramoto et al., 2007). Using PCR based methods KHV DNA has been detected at high levels in water samples collected at 8 sites along the Yura river system during, and 3 months after a KHV disease outbreak at water temperatures ranging from 28.4 down to 14.5°C (Minamoto et al., 2009b). In Lake Biwa, Japan KHV was found to be widely distributed throughout the lake 5 years after the first observed KHV outbreak. Mean concentrations of KHV in the lake water showed annual variation, with a peak in the summer and a trough in winter, and the virus was most prevalent in turbid, eutrophic water found in the lake margins (Minamoto et al., 2009a).

3.1.1.6. Article 7(a)(vi) The routes and speed of transmission of the disease between animals, and, when relevant, between animals and humans

Routes of transmission

Parameter 1 – Types of routes of transmission from animal to animal (horizontal, vertical)

Vertical transmission has not been demonstrated to date and horizontal transmission is thought to be the primary transmission route. Horizontal transmission of KHV could occur either by direct contact between fish or by indirect transmission through the water. KHV can enter the host through skin or pharyngeal periodontal mucosa (Raj et al., 2011; Fournier et al., 2012). Horizontal transmission in natural ponds seems accentuated in hot spots of carp breeding behaviour and mating (Uchii et al., 2011), where direct interactions between fish maybe high (Raj et al., 2011). Several potential vectors could be involved in the indirect transmission of KHV including fish droppings (Dishon et al., 2005), plankton (Minamoto et al., 2011), sediments (Honjo et al., 2012) and aquatic invertebrates feeding by water filtration (Kielpinski et al., 2010). However, water is likely to be the dominant indirect transmission route (Minamoto et al., 2009b), as KHV is shed into the environment from gills, skin and gut and can remain infective in water and sediment for substantial periods (Perelberg et al., 2003; Pikarsky et al., 2004; Dishon et al., 2005; Shimizu et al., 2006; Haramoto et al., 2007; Costes et al., 2009; Minamoto et al., 2009a; Adamek et al., 2013).

Parameter 2 – Types of routes of transmission between animals and humans (direct, indirect, including food-borne)

Not applicable – KHV is not known to infect humans.

Speed of transmission

Parameter 3 – Incidence between animals and, when relevant, between animals and humans

No available data or published studies document a reliable time series of prevalence change in natural infections; however, experimental studies suggest that as the pathogen is transmitted through the water (in addition to via direct contact), infection rates post introduction are high and lead to the majority of the population becoming infected over a period of a few days. The relatively short duration of mortality observed in many natural outbreaks may also suggest that the majority of infection occurs within a short timeframe.

Parameter 4 – Transmission rate (beta) (from R_0 and infectious period) between animals and, when relevant, between animals and humans

No available data or published studies allow R_0 to be determined; however, as stated above, most of the population apparently becomes infected over a few days and the limited timeframe over which mortality is observed also suggests that most infection occurs within a short timeframe. No transmission from fish to humans has been recorded and the virus is not thought to have any zoonotic potential.

3.1.1.7. Article 7(a)(vii) The absence or presence and distribution of the disease in the Union, and, where the disease is not present in the Union, the risk of its introduction into the Union

Presence and distribution

Parameter 2 – Type of epidemiological occurrence (sporadic, epidemic, endemic) at MS level

In Europe, reports of widespread mass mortality have been notified in carp farms and fisheries in Germany, Poland and the UK (Bergmann et al., 2006; Taylor et al., 2010a,b; Gotesman et al., 2013). The disease is also known to occur in, or has been recorded in fish imported into, Austria, Belgium,

the Czech Republic, Denmark, France, Hungary, Italy, Luxembourg, the Netherlands, Ireland and Switzerland (Haenen et al., 2004; Pokorova et al., 2010; McCleary et al., 2011; Pretto et al., 2013). Most recently, KHVD outbreaks have been reported to the OIE from Romania, Slovenia, Spain and Sweden (OIE, online). Three novel KHV-like viruses were also identified by PCR in the Netherlands, UK, Austria and Italy. Carp carrying these KHV variants did not show clinical signs consistent with KHV infection and originated from locations with no actual KHV outbreaks. In addition to these published records, the OIE compiles the occurrence of KHV globally which can be viewed through the WAHIS[1] interface. The results from this database are presented in Appendix A.

Risk of introduction

Parameter 3 – Routes of possible introduction

Worldwide trade in live common and koi carp is generally thought to be responsible for the spread of the virus between countries. Spread is largely thought to have occurred prior to methods of detection being available (OIE, online). The disease is now known to occur in, or has been reported in fish imported into, at least 28 different countries (OIE, online). Susceptible species are traded for the purpose of aquaculture, food and the ornamental trade. Controls are in place to prevent the movement of fish for aquaculture and the ornamental trade from countries with the disease to those confirmed free of the disease; however, these measure were only implemented after the pathogen was listed in EU legislation. In the case of KHV, this occurred long after the pathogen emerged, meaning few effective control procedures were in place early enough to prevent its rapid spread. Although fish destined for the ornamental trade and as food commodities should not pose a risk to aquaculture or fisheries, it is known that they are regularly introduced into open systems and therefore pose a significant hazard (Taylor et al., 2011).

At a local level, the movement of live fish poses the greatest risk of spreading the pathogen; however, the movement/transfer of water and equipment (such as anglers nets) may also contribute to the spread of the pathogen.

Parameter 4 – Number of animal moving and/or shipment size

The movement and trade of live KHV susceptible species occurs for several purposes, including; aquaculture, as a food commodity, the ornamental retail sector and direct supply of hobbyists. The trading patterns are complex (Peeler and Taylor, 2011), Member States (MSs) will record imports and movements for the purpose of aquaculture and possibly hold records of commodity trade; however, these records only constitute a small amount of the relevant trade and are not stored in a centralised repository and are therefore not readily available. Significant knowledge gaps relating to this section therefore exist. In the UK, records of imports kept at each border inspection post (BIP) suggest that in 2006 4,684 consignments of coldwater ornamental fish (number and species unknown) were imported into the main UK BIPs. These came from 116 different suppliers from across 12 non-EU countries (Taylor et al., 2013). In comparison, trade in fish destined for aquaculture (or fisheries) in 2006 was small, with only 93 consignments being imported, all of which originated in the EU. Movement of fish within the UK in 2006 was more significant, with 2,642 movements of potentially susceptible fish supplied by 426 UK sites to 1773 UK sites (Taylor et al., 2013).

Parameter 5 – Duration of infectious period in animal and/or commodity

As discussed in the above sections, although knowledge gaps relating to latency of KHV exist, the best data available at present suggests fish exposed to the virus may remain infected for their lifetime.

Parameter 6 – List of control measures at border (testing, quarantine, etc.)

EU legislation (Council Directive 2006/88/EC[2]) prevents trade in fish species susceptible to listed disease from countries with a lower health status than the receiving country. Countries listed as free from KHV, or under an official control and eradication programme should therefore only receive fish from approved KHV free countries. Import should occur through a BIP, where inspectors will check that consignments of susceptible fish have a health certificate provided by the exporting country that confirms they originate from a disease free compartment. Fish imported for the purpose of direct consumption are exempt from these regulations, and may pose a risk if stocked or held in non-

[1] http://www.oie.int/animal-health-in-the-world/the-world-animal-health-information-system/the-oie-data-system/

[2] Council Directive 2006/88/EC of 24 October 2006 on animal health requirements for aquaculture animals and products thereof, and on the prevention and control of certain diseases in aquatic animals. OJ L 328, 24.11.2006, p. 14–56.

biosecure systems prior to slaughter. In addition to these international controls, testing at the BIPs to confirm imported consignments are free from pathogens of concern constitutes a part of the EU controls (e.g. KHV). It is not known how many countries employ such additional checks meaning a knowledge gap exists, but given the volume of trade it is likely that only a small proportion of consignments can be tested. Stockists of fish within MSs are encouraged to adopt good biosecurity practices (such as quarantine) and ensure they know the origin of their stock, but a knowledge gap exists relating to how frequently these recommendations are adhered to.

Parameter 7 – Presence and duration of latent infection and/or carrier status

As discussed in the above sections, fish exposed to the virus may remain infected for their lifetime.

3.1.1.8. Article 7(a)(viii) The existence of diagnostic and disease control tools

Diagnostic tools

Parameter 1 – Existence of diagnostic tools

Diagnosis of KHVD in clinically affected fish can be achieved by numerous methods. The manual of diagnostic tests for aquatic animals lists gross clinical signs, histopathological alterations and transmission electron microscopy as suitable for presumptive diagnosis of KHVD and descriptions of these are documented in OIE (OIE, online). However, final diagnosis relies on direct detection of viral DNA or virus isolation and identification (OIE, online). The OIE manual (OIE, online) details virus detection methods that include single-round conventional PCR assays, virus isolation in cell culture, indirect fluorescent antibody tests on kidneys imprints and formalin fixed paraffin wax sections followed by confirmatory identification using PCR and nucleotide sequencing. Current virus isolation and culture methods are not considered to be very sensitive, and are therefore not reliable for detection of KHVD. None of the current diagnostic tests are fully validated and the manual suggests that diagnosis of KHVD disease should not rely on just one test but rather a combination of two or three that include clinical examination as well as virus detection (OIE, online). Non-destructive testing of fish relies on the testing of blood. Pokorova et al. (2010), Bergmann et al. (2009) and Eide et al. (2011) applied PCR-based methods to successfully detect KHV in the blood of infected carp, and Taylor et al. (2010a,b) an applied antibody enzyme-linked immunosorbent assay (ELISA) to determine whether farmed, wild and imported (Carp) in the UK had been exposed to the virus. Although it is likely that both approaches are specific to KHV, a knowledge gap exists surrounding the sensitivity of these methods especially in the case of sub-clinical infections (Bergmann et al., 2009; Pokorova et al., 2010; Taylor et al., 2010a; Eide et al., 2011).

Control tools

Parameter 2 - Existence of control tools

No treatments for KHV exist, and control relies on preventing the introduction and spread of the pathogen through a combination of good biosecurity, eradicating infected populations and applying movement restrictions to infected sites. However, there is no published evidence on which to assess the biological effectiveness or economic benefit of these generic approaches to disease control. Modelling based studies by Taylor et al. (2011) suggest that in the case of the UK fish imported into the country for the purpose of the ornamental trade and illegally stocked into fisheries are likely to play a significant role in determining the effectiveness of control measures (Taylor et al., 2011). Without controlling such introductions, the effectiveness of other control measures is likely to be limited. This study also suggested that a high case detection rate (i.e. high diagnostic sensitivity, including subclinical infections) was critical to an effective control strategy.

Alternative measures of control may be through an immunisation protocol (involving exposure to live virus and water temperature manipulation) which was developed and has shown to be efficacious (Perelberg et al., 2003; Ronen et al., 2003). A commercial attenuated vaccine has also been produced (KoVac). Vaccination and immunisation of populations may also provide a useful tool as part of a control and eradication programme.

3.1.2. Article 7(b) The impact of diseases

3.1.2.1. Article 7(b)(i) The impact of the disease on agricultural and aquaculture production and other parts of the economy

The level of presence of the disease in the Union

Parameter 1 – Number of MSs where the disease is present

In Europe, 18 MSs have reported KHV in some form. Reports of widespread mass mortality have been notified in carp farms and fisheries in Germany, Poland and the UK (Bergmann et al., 2006; Taylor et al., 2010a; Gotesman et al., 2013). The disease is also known to occur in, or has been recorded in fish imported into, Austria, Belgium, the Czech Republic, Denmark, France, Hungary, Italy, Luxembourg, the Netherlands, Ireland and Switzerland (Haenen et al., 2004; Pokorova et al., 2010; McCleary et al., 2011; Pretto et al., 2013). Most recently, KHVD outbreaks have been reported to the OIE from Romania, Slovenia, Spain and Sweden (OIE, online). Three novel KHV-like viruses have also been identified by PCR in the Netherlands, UK, Austria and Italy. Although KHV is notifiable to the OIE, reporting is down to the individual MSs and this is reliant on there being an effective means of surveillance in each country so knowledge gaps may exist.

The loss of production due to the disease

Parameter 2 – Proportion of production losses (%) by epidemic/endemic situation

In the 3 years since the first outbreak in Israel in 1998, KHVD spread to 90% of the carp farms (Perelberg et al., 2003). By the end of 1998, the losses of common carp and ornamental carp were estimated to be $1.2 million and $0.8 million annually. The loss of production of food carp in Israel in 1999 was estimated to be 1,500 tonnes (Mires, 2001).

In Japan, the disease first occurred in a lake used for common carp production, and in approximately one month over 1,200 tonnes of fish had died, representing 25% of the annual production of the lake (Sano et al., 2004a) with a value of approximately $2.55 million (Waltzek and Hedrick, 2004). All remaining cultured carp in the lake were destroyed as a control measure (Sano et al., 2004b). The disease has only been detected in common carp and not in koi carp in Japan (Sano et al., 2004b).

Over 5,000 koi farmers in East Java were affected by the first outbreak of KHVD in Indonesia (Sunarto et al., 2004) and the economic loss was estimated to be $0.5 million within the first three months of the outbreak. The socioeconomic impact on affected communities was estimated to be $5 million in July of 2002, but by December of that year following the rapid spread of KHVD the figure had doubled; as of December 2003 the losses were estimated to be $15 million.

In just two regions of Germany, the costs to three farms in 2003 were $435,500 and to one farm in 2004 was $417,000 (Schlotfeldt, 2004).

3.1.2.2. Article 7(b)(ii) The impact of the disease on human health

Not applicable – KHV is not known to infect humans.

3.1.2.3. Article 7(b)(iii) The impact of the disease on animal welfare

Parameter 1 – Severity of clinical signs at case level and related level and duration of impairment

Fish infected with KHV and kept at a permissive temperature (i.e. > 16°C), die between 5 and 22 days post-infection with peak of mortality occurring between days 8 and 12 post-infection (Hedrick et al., 2000; Perelberg et al., 2003; Rakus et al., 2009; Fournier et al., 2012). Furthermore, KHV-infected fish are more susceptible to secondary infections by bacterial, parasitic or fungal pathogens, which may contribute to the mortalities observed in the infected population (McDermott and Palmeiro, 2013).

The first clinical signs usually appear 2–3 days post-infection. In carp, severe necrosis of the gills is the major clinical sign (likely the predominant cause of death), but they also generally express the following: folding of the dorsal fin; increased respiratory frequency; gathering near well-aerated areas; skin changes including gradual hyperaemia at the base of fins, increased (sometimes decreased) mucus secretion, haemorrhages and ulcers on the skin, sloughing of scales and fin erosion, sandpaper-like texture of the skin, skin herpetic lesions; gasping at the water surface; lethargy (lying at the bottom of the tank, hanging in head-down position in the water column) associated with anorexia; sunken eyes; neurological symptoms with erratic swimming and loss of equilibrium (Walster, 1999;

Hedrick et al., 2000; McDermott and Palmeiro, 2013; Rakus et al., 2013). None of these clinical signs are specific to KHV disease.

3.1.2.4. Article 7(b)(iv) The impact of the disease on biodiversity and the environment

Biodiversity

Parameter 1 – Endangered wild species affected: listed species as in CITES and/or IUCN list

None of the susceptible species listed are classed as endangered.

Parameter 2 – Mortality in wild species

Although carp (and its variants) are widely cultured or stocked, in many countries they can also be regarded as a wild species. In the case of natural infections in open water systems, although several studies suggest that mortality due to KHV (in lake and farm systems) can be high, knowledge gaps exist as due to difficulties in determining the total host population size, thus no reliable estimates of percentage mortality are available in case sites. In Taiwan, data from cultured carp outbreaks showed mortality of 70–100% (Chen et al., 2015); however, information on mortality rates in Europe is limited. Data on cases in the UK lakes supplied by Cefas (Taylor, 2016) show total mortalities to occur when water temperatures were in excess of 16°C, and to be highly variable between sites (ranging between 1 and > 2,000). Percentage values surrounding these figures are highly speculative, but were thought to be around 10–20% on average, but could be as high as 90% in exceptional circumstances. The duration over which mortality was observed is also variable, but generally occurred over a period of 12–20 days. The duration over which mortality occurs is likely to be determined by the transmission dynamics occurring within a population and temperature.

Environment

Parameter 3 – Capacity of the pathogen to persist in the environment and cause mortality in wildlife

Fish surviving infection by KHV are likely to remain carriers for life (discussed in sections above); however, even in the absence of infected fish the virus may persist in the sediment for some time, posing a risk of subsequent infection (see Section 3.1.1.5 Parameter 4). For example, in Japan, using PCR detection methods to screen environmental water samples, KHV was detected at high levels at 8 sites along the Yura river system during, and 3 months after an episode of mass mortality caused by KHV disease. KHV was also found to be widely distributed throughout Lake Biwa, Japan 5 years after the first observed KHV outbreak (Minamoto et al., 2009a, 2012; Uchii et al., 2009, 2011).

3.1.3. Article 7(c) Its potential to generate a crisis situation and its potential use in bioterrorism

Parameter 1 – Listed in OIE/CFSPH classification of pathogens

KHV is an OIE listed pathogen.

Parameter 2 – Listed in the Encyclopaedia of Bioterrorism Defence of Australia Group

It is not listed.

Parameter 3 – Included in any other list of potential bio- agro-terrorism agents

It is not listed.

3.1.4. Article 7(d) The feasibility, availability and effectiveness of the following disease prevention and control measures

3.1.4.1. Article 7(d)(i) Diagnostic tools and capacities

Availability

Parameter 1 – Officially/internationally recognised diagnostic tool, OIE certified

The KHV chapter in the OIE Diagnostic manual (OIE, online) provides information on the most commonly used quantitative assay for detection of KHV, the Gilad Taqman real-time PCR assay (Gilad et al., 2004). Real-time Taqman PCR is now a very common diagnostic procedure that has been shown to detect and quantitatively assess very low copy numbers of target nucleic acid sequences.

Furthermore, Taqman PCR avoids much of the contamination risk inherent to nested PCR assays by minimising the handling of samples through automation during sample preparation and thermal cycling procedures.

Effectiveness

Parameter 2 – Se and Sp of diagnostic test

Bergmann et al. (2010a–c) compared existing and newly developed PCRs for the detection of KHV DNA (Bergmann et al., 2010c). A modified real-time PCR (Gilad et al., 2004), combined with an internal control system (IC2), was used as a reference standard. The most sensitive PCR assays, capable of detecting 5–10 KHV DNA genomic equivalents, were the Gilad Taqman real-time qPCR, a nested Bergmann/Gilad assay (Bergmann et al., 2006) and a newly-developed, one tube semi-nested PCR. In term of analytical specificity, the PCR assays were tested against carp pox virus, goldfish herpesvirus, channel catfish herpesvirus and herpesvirus anguillae, and they recognise KHV only. Measures of diagnostic sensitivity and specificity of this PCR assays are not reported.

The Bergmann study also discovered 'KHV variants' in two field samples which could not be detected by the Bercovier TK PCR. Also a negative influence of sample pooling was shown with field samples tested by real-time PCR. However, the comparative testing mostly used KHV DNA in plasmids and extracted from KHV-infected cell cultures. The field samples were comprised of 18 KHV-infected carp and 3 KHV-exposed carrier fish. The Bercovier TK PCR assays compared in this study (single-round and nested) were run with an annealing temperature of 55°C. This is a higher temperature than the 52°C stated in the original paper (Bercovier et al., 2005) and may account for the lack of sensitivity shown by these assays.

Feasibility

Parameter 3 – Type of sample matrix to be tested (blood, tissue, etc.)

According to the OIE manual (OIE, online): 'Gill, kidney, and spleen are the organs in which KHV is most abundant during overt infection' and should therefore be targeted.

3.1.4.2. Article 7(d)(ii) Vaccination

Availability

Parameter 1 – Types of vaccines available on the market (live, inactivated, DIVA, etc.)

An inactivated vaccine candidate exists that consists of formalin-inactivated KHV contained in a liposomal compartment (Yasumoto et al., 2006). A conventional anti-KHV attenuated vaccine has also been developed which is used commercially in Israel (produced by KoVac); this is however pathogenic to small fish and there is the possibility of reversion to a pathogenic phenotype (Yasumoto et al., 2006). The development of alternative attenuated recombinant vaccines is also being investigated (Boutier et al., 2015).

Parameter 2 – Availability/production capacity (per year)

This is unknown and constitutes a knowledge gap.

Effectiveness

Parameter 3 – Field protection as reduced morbidity (as reduced susceptibility to infection and/or to disease)

Inactivated vaccine reduces mortality by 70% (Yasumoto et al., 2006).

Parameter 4 – Duration of protection

This is unknown and constitutes a knowledge gap.

Feasibility

Parameter 5 – Way of administration

Inactivated vaccine administered through feed (oral), attenuated administered by immersion in water (bath).

3.1.4.3. Article 7(d)(iii) Medical treatments

There is no available medical treatment.

3.1.4.4. Article 7(d)(iv) Biosecurity measures

Parameter 1 – Available biosecurity measures

Biosecurity to prevent introduction of the pathogen from live fish centres around safe sourcing of stock from known disease free origin. Testing of consignments upon receipt and prior to introduction to other stocks is at the discretion of the receiving country or site. Quarantining stock on arrival is complicated by latency and the existence of permissive temperatures. Heat ramping to induce viral shedding may be required in addition to the use of naïve sentinel fish for quarantine to be an effective biosecurity measure.

Effectiveness

Parameter 2 – Effectiveness of biosecurity measures in preventing the pathogen introduction

Safe sourcing of fish is the most effective measure, but this is complicated by the fact that fish surviving infection show no clinical signs of disease and may carry virus at such low levels they are difficult to detect by molecular methods. Serological testing may provide additional assurance that fish are free from KHV, though the specificity of current serological tests needs further evaluation. Fish that have survived clinical infection are unlikely to re-express clinical signs during quarantine, therefore this measure is likely to have little value unless used in combination with sentinel fish and a stressor (such as heat ramping) to induce recrudescence of the virus.

Feasibility

Parameter 3 – Feasibility of biosecurity measure

The complexity of both international and national trading patterns of cyprinids, in addition to interactions between different industry sectors, can make it difficult to be sure of the origin of fish. Testing consignments of fish on arrival at border inspection posts is feasible, but the volume of trade means that only a small proportion of fish are likely to be tested. Additionally, there are logistical issues with holding fish in biosecure conditions to good welfare standards whilst awaiting test results for the purpose of quarantine.

3.1.4.5. Article 7(d)(v) Restrictions on the movement of animals and products

Availability

Parameter 1 – Available movement restriction measures

At the international level, Council Directive 2006/88/EC[3] allows the restriction of imports of fish from countries with a lesser health status with regard to KHV than the receiving country. To date, however, only three countries within the EU have been recognised as KHV free (commission Implementing Decision (EU) 2015/1310[4]), and therefore very few countries can restrict the import of susceptible species from known KHV positive countries. At the national level, movement restrictions can be applied to KHV positive sites, which should remain in force until the site has depopulated and disinfected to the satisfaction of the competent authority, or has gone through at least 4 consecutive years of testing negative for the virus and showing no signs of clinical disease. Additional biosecurity measures such as disinfectant baths should also be introduced to sites under such circumstances. These controls all rely on an effective surveillance, testing and reporting system.

Effectiveness

Parameter 2 – Effectiveness of restriction of animal movement in preventing the between farm spread

Cefas have observed very little recurrence of disease at KHV positive sites suffering clinical outbreaks of KHV in the UK. However, the effectiveness of movement restrictions is complicated by the

[3] Council Directive 2006/88/EC of 24 October 2006 on animal health requirements for aquaculture animals and products thereof, and on the prevention and control of certain diseases in aquatic animals. OJ L 328, 24.11.2006, p. 14–56.

[4] Commission Implementing Decision (EU) 2015/1310 of 28 July 2015 amending Annex I to Decision 2009/177/EC as regards disease-free status for the whole territory of Croatia for koi herpes virus (KHV) disease (Text with EEA relevance). OJ: JOL_2015_200_R_0008

potential for latency of the virus in surviving stock. Taylor et al. (2010a,b) demonstrated that KHV seropositive sites could be traced back to other seropositive sites. Whether such movements lead to the expression of clinical disease is likely to be depend on whether the fish are still infected and several climate (e.g. temperature) and site level factors (stock density at receiving site) at the time fish are transferred. If fish are moved whilst the temperature is below 16°C and/or stock densities at the receiving site are low, clinical disease may not occur and the virus could potentially spread silently.

Feasibility

Parameter 3 – Feasibility of restriction of animal movement

The ability to apply movement restrictions will vary depending on the resources available within each MS to perform and effective surveillance and detection program, and, enforce movement restrictions and measures applied to infected sites.

3.1.4.6. Article 7(d)(vi) Killing of animals

Availability

Parameter 1 – Available methods for killing animals

A questionnaire sent to EU MSs asking about methods used for slaughter of carp found that the following methods were commonly used: asphyxia following percussion, electrical stunning and percussion. In the context of disease controls, carp farms can be destocked netting the fish into tanks where they can be euthanised using an overdose of anaesthetic, e.g. MS222 or phenoxiethanol (it should be noted that there is no product licensed in Europe to our knowledge for euthanasia). Alternatively, percussive stunning (using a 'priest') can be used prior to killing by slitting the gills (or evisceration). This method is used commercially. Captive bolt methods are under development. Electrical stunning is possible but in general devices are not widely available. Methods of killing are covered in detail in an EFSA paper (Algers et al., 2009).

In extensive ponds and stillwater fisheries removal of all fish, prior to slaughter, requires the water to be drained. The hydrology and soil type means this is impractical in many situations. Farmers may seek to harvest fish for human consumption to reduce financial losses. These fish must be slaughtered and processed in approved premises so that processing waste is disposed of in a biosecure manner.

Effectiveness

Parameter 2 – Effectiveness of killing animals (at farm level or within the farm) for reducing/stopping spread of the disease

Killing and removal of fish from an infected farm effectively eliminates further contamination of the water, equipment, etc., and thus is effective in reducing spread of the disease via water or fomite transmission. Water, sediment, etc. will remain contaminated, if the site is not emptied, cleaned and disinfected, and thus a source of infection for a period after the farm has been destocked. Killing by exsanguination or evisceration will result in further contamination and in this respect is less preferable than an overdose of anaesthetic.

Feasibility

Parameter 3 – Feasibility of killing animals

Killing using an overdose of an anaesthetic (e.g. MS222) administered to fish kept in small volumes of water is the most feasible method available. Detailed protocols setting tank sizes and dosing per biomass of fish are not publicly available. Percussion stunning using a 'priest' followed by exsanguination or evisceration is most suitable for small numbers of fish. Electrical stunning is feasible if the appropriate equipment is available, and they are not widely used. A knowledge gap exists as there are no published data comparing rates of slaughter by different methods.

3.1.4.7. Article 7(d)(vii) Disposal of carcasses and other relevant animal by-products

Availability

Parameter 1 – Available disposal option

Health rules for animal by-products and derived products (repealing Regulation (EC) No 1774/2002[5]), fish killed for the control of a listed disease constitute category I waste. Category I waste must be rendered at an approved establishment. A list of approved premises by MS can be found at http://ec.europa.eu/food/safety/animal-by-products/approved-establishments/index_en.htm. Carcasses must be transported to an approved premise by approved transport in a sealed container.

Effectiveness

Parameter 2 – Effectiveness of disposal option

Rendering is an extremely effective disposal method of destroying pathogens. Rendering converts waste animal tissue into stable, value added products. The process simultaneously dries the material and separates the fat from the bone and protein. Tissues are macerated, heated and then subject to centrifugal separation.

Feasibility

Parameter 3 – Feasibility of disposal option

Rendering is a feasible option if an approved establishment is located within a reasonable distance from the farm, is willing to accept fish carcasses and approved transport is available.

3.1.5. Article 7(e) The impact of disease prevention and control measures

3.1.5.1. Article 7(e)(i) The direct and indirect costs for the affected sectors and the economy as a whole

Parameter 1 – Cost of control (e.g. treatment/vaccine, biosecurity)

A knowledge gap exists as there are no published data on the cost of control of KHV. There are no treatments and no vaccine has been licensed in Europe. Biosecurity for KHV on carp farms include measures to prevent introduction on fomites, e.g. foot baths, cleaning of vehicles entering the site, disinfection of equipment entering the site etc. These measures are part of good management and are not specific to KHV. Purchasing stock from known KHV free sites is the key biosecurity measure to maintain freedom from KHV. The supply of stock from approved free premises may be limited and more costly than stock from non-approved sites, however, no data are available on which to asses a price differential. A purchaser could require stock to be tested prior to purchase. This is an expensive option and probably not viable except for high value ornamental carp.

Parameter 2 – Cost of eradication (culling, compensation)

There are no published data for the costs associated with eradication. They will, however, depend on the size and structure of a site. Many carp farms in Europe are very large scale (with ponds covering more than one hectare). Eradication is technically challenging and very time consuming. Netting and killing the fish would take a team of four qualified staff up to 5 days. Based on the experience in the UK, the total cost including disposal is likely to be in the region of 20,000 euros. A smaller farm where carp are raised in accessible ponds can be destocked for half this amount. Most MS do not pay compensation. Large carp produced for angling in the UK are valuable. A 10-kg fish costs approximately £750, while small carp at round 5 kg are sold for £100. Carp produced for the table have a lower value. Farmgate prices for carp in Europe were not available but it retails at about 2.5 euros per kg.

Parameter 3 – Cost of surveillance and monitoring

Under Council Directive 2006/88/EC,[3] the competent authority has an obligation to undertake authorisation visits to farms on a regular basis. While these activities are an important element of surveillance, the costs cannot be attributed to a single disease. The key obligation of competent

[5] Regulation (EC) No 1774/2002 of the European Parliament and of the Council of 3 October 2002 laying down health rules concerning animal by-products not intended for human consumption. OJ L 273, 10.10.2002, p. 1–95.

authorities is to investigate suspected cases of KHV. The cost of a single investigation including diagnostics is approximately 1000 euros. In the UK, 30–80 outbreaks are investigated each year at a cost of 30–80,000 euros.

Parameter 4 – Trade loss (bans, embargoes, sanctions) by animal product

KHV is listed under EU legislation and it is also notifiable to the OIE. EU MS can establish approved free compartments, zones and countries and then restrict trade in susceptible species (e.g. carp) to zones of the same status. However, very little carp production in the EU is in approved free areas. Internationally the picture is the same – very little production takes place in areas self-declared free. Effectively, there has been very little economic impact via trade loss due to KHV within the EU or internationally.

Parameter 5 – Importance of the disease for the affected sector (% loss or € lost compared to business amount of the sector)

In the UK, KHV has impacted carp fisheries (farms have largely been unaffected). Outbreaks occur on 10–24 fisheries per year, causing losses of upwards of 10% of carp. There are approximately over 5,000 carp fisheries in the UK. Thus, the impact of the disease compared to the size of the sector is negligible. An individual fishery suffers direct losses due to mortality and the implementation of control measures (including restrictions on stocking). These losses have not been estimated, however, they have not resulted in any fishery ceasing to trade to date. It was estimated that in Germany the costs of an outbreak in a farm producing 20 tonnes of fish ranges from €150,000 to €250,000 (including disinfection, removal of carcasses, cleaning and partly restocking) (Brauer et al., 2004).

3.1.5.2. Article 7(e)(ii) The societal acceptance of disease prevention and control measures

No published studies on the societal acceptance of disease prevention and control measures for KHV were found. In the UK, disease control measures on carp fisheries, farms and in ornamental fish retailers are widely accepted by stakeholders. At a societal level, there has been little opposition to destocking of farms or fisheries undertaken as part of a disease control programme.

3.1.5.3. Article 7(e)(iii) The welfare of affected subpopulations of kept and wild animals

Parameter 1 – Welfare impact of control measures on domestic animals

Holding fish for the purpose of quarantine or whilst awaiting test results relies on having suitable biosecure systems to hold the fish in a sustainable manner. Such systems must have sufficient space to hold the stock, have the ability to feed the fish and maintain the environmental quality of the water they are held in. Where the virus is detected and the decision is made to cull the stock, care must be taken to employ a suitable humane method that can be applied to a potentially high number of fish. In many countries, the availability of suitable holding facilities and/or high throughput culling methods may be limited.

Parameter 2 – Wildlife depopulation as control measure

Due to the extensive nature of the systems containing wild carp populations and dependency on the water they live in for other purposes (e.g. drinking, recreation, etc.), depopulation of sites using biocides is not likely to be feasible. In small self-contained waters, biocides may be applied or the site depopulated trough draining or other methods (e.g. netting).

3.1.5.4. Article 7(e)(iv) The environment and biodiversity

Environment

Parameter 1 – Use and potential residuals of biocides or medical drugs in environmental compartments (soil, water, feed, manure)

Not applicable.

Biodiversity

Parameter 2 – Mortality in wild species

In many European countries, carp can be classed as both a domestic and wild species and there is a great degree of interaction between the two population types. Many of the outbreaks recorded to

date have occurred in fishery/lake populations of carp, so the impact to these wild/semiwild populations can be as great as observed in farms (Taylor et al., 2010a,b).

3.2. Assessment according to Article 5 criteria

This section presents the results of the expert judgement on the criteria of Article 5 of the AHL about KHVD (Table 1). The expert judgement was based on Individual and Collective Behavioural Aggregation (ICBA) approach described in detail in the opinion on the methodology (EFSA AHAW Panel, 2017). Experts have been provided with information of the disease fact-sheet mapped into Article 5 criteria (see supporting information, Annex A), based on that the experts indicate their Y/N or 'na' judgement on each criterion of Article 5, and the reasoning supporting their judgement.

The minimum number of judges in the judgement was 10. The expert judgement was conducted as described in the methodological opinion (EFSA AHAW Panel, 2017). For details on the interpretation of the questions, see Appendix B of the methodological opinion (EFSA AHAW Panel, 2017).

Table 1: Outcome of the expert judgement on the Article 5 criteria for Koi herpes virus disease (KHVD)

Criteria to be met by the disease: According to AHL, a disease shall be included in the list referred to in point (b) of paragraph 1 of Article 5 if it has been assessed in accordance with Article 7 and meets all of the following criteria		**Final outcome**
A(i)	The disease is transmissible	Y
A(ii)	Animal species are either susceptible to the disease or vectors and reservoirs thereof exist in the Union	Y
A(iii)	The disease causes negative effects on animal health or poses a risk to public health due to its zoonotic character	Y
A(iv)	Diagnostic tools are available for the disease	Y
A(v)	Risk-mitigating measures and, where relevant, surveillance of the disease are effective and proportionate to the risks posed by the disease in the Union	NC
At least one criterion to be met by the disease: In addition to the criteria set out above at point A(i)–A(v), the disease needs to fulfil at least one of the following criteria		
B(i)	The disease causes or could cause significant negative effects in the Union on animal health, or poses or could pose a significant risk to public health due to its zoonotic character	Y
B(ii)	The disease agent has developed resistance to treatments and poses a significant danger to public and/or animal health in the Union	na
B(iii)	The disease causes or could cause a significant negative economic impact affecting agriculture or aquaculture production in the Union	Y
B(iv)	The disease has the potential to generate a crisis or the disease agent could be used for the purpose of bioterrorism	N
B(v)	The disease has or could have a significant negative impact on the environment, including biodiversity, of the Union	NC

Colour code: green = consensus (Yes/No); yellow = no consensus (NC); red = not applicable (na), i.e. insufficient evidence or not relevant to judge.

3.2.1. Non-consensus questions

This section displays the assessment related to each criterion of Article 5 where no consensus was achieved in form of tables (Tables 2–4). The proportion of Y, N or na answers are reported, followed by the list of different supporting views for each answer.

Table 2: Outcome of the expert judgement related to criterion 5 A(v)

Question		Final outcome	Response		
			Y (%)	N (%)	na (%)
A(v)	Risk-mitigating measures and, where relevant, surveillance of the disease are effective and proportionate to the risks posed by the disease in the Union	NC	90	10	0

NC: non-consensus; number of judges: 10.

Reasoning supporting the judgement

Supporting Yes:

- Biosecurity and movement controls limit the spread. At least 18 MSs have reported the detection of KHV.
- There is a very little recurrence of disease where it has been previously diagnosed.
- The impact of the disease compared to the size of the sector is negligible and therefore the measures are proportionate.
- Diagnosis of KHV in clinically affected fish relies on numerous methods, as described in the OIE manual of diagnostic tests for aquatic animals.
- If clinical signs are apparent, the disease can be detected.

Supporting No:

- Current available diagnostic tools and treatments are limited. Vaccines are not available in the EU. None of the current diagnostic tests are fully validated: the level of sensitivity of these methods is still unclear, especially in the case of subclinical infections.
- There is a high risk of subclinical infections despite the control measures available.

Table 3: Outcome of the expert judgement related to criterion 5 B(v)

Question		Final outcome	Response		
			Y (%)	N (%)	na (%)
B(v)	The disease has or could have a significant negative impact on the environment, including biodiversity, of the Union	NC	80	20	0

NC: non-consensus; number of judges: 10.

Reasoning supporting the judgement

Supporting Yes:

- There may be an impact on biodiversity considering wild carp, although none of the susceptible species listed are classed as endangered.
- Carp is an allochthonous species, the disease may spread to and among native fish.

Supporting No:

- Apparently, there is no or little recurrence after an outbreak despite long persistence of the virus in the environment and fish being tested positive, thus there is no long-term impact.

3.2.2. Outcome of the assessment of Koi herpes virus disease (KHV) according to criteria of Article 5(3) of the AHL on its eligibility to be listed

As from the legal text of the AHL, a disease is considered eligible to be listed as laid down in Article 5 if it fulfils all criteria of the first set from A(i) to A(v) and at least one of the second set of criteria from B(i) to B(v). According to the assessment methodology (EFSA AHAW Panel, 2017), a criterion is considered fulfilled when the outcome is 'Yes'. According to the results shown in Table 1, KHVD complies with criteria A(i), A(ii), A(iii) and A(iv) and the assessment is inconclusive on compliance with

criterion 5 A(v). Therefore, it is inconclusive whether KHVD can be considered eligible to be listed for Union intervention as laid down in Article 5(3) of the AHL.

3.3. Assessment according to Article 9 criteria

This section presents the results of the expert judgement on the criteria of Annex IV referring to categories as in Article 9 of the AHL about KHVD (Tables 4–8). The expert judgement was based on ICBA approach described in detail in the opinion on the methodology. Experts have been provided with information of the disease fact-sheet mapped into Article 9 criteria (see supporting information, Annex A), based on that the experts indicate their Y/N or 'na' judgement on each criterion of Article 9, and the reasoning supporting their judgement. The minimum number of judges in the judgement was 10. The expert judgement was conducted as described in the methodological opinion (EFSA AHAW Panel, 2017). For details on the interpretation of the questions, see Appendix B of the methodological opinion (EFSA AHAW Panel, 2017).

Table 4: Outcome of the expert judgement related to the criteria of section 1 of Annex IV (category A of Article 9) for Koi herpes virus disease (KHVD)

Criteria to be met by the disease: The disease needs to fulfil all of the following criteria		**Final outcome**
1	The disease is not present in the territory of the Union OR present only in exceptional cases (irregular introductions) OR present in only in a very limited part of the territory of the Union	NC
2.1	The disease is highly transmissible	NC
2.2	There be possibilities of airborne or waterborne or vector-borne spread	Y
2.3	The disease affects multiple species of kept and wild animals OR single species of kept animals of economic importance	Y
2.4	The disease may result in high morbidity and significant mortality rates	NC
At least one criterion to be met by the disease: In addition to the criteria set out above at points 1–2.4, the disease needs to fulfil at least one of the following criteria		
3	The disease has a zoonotic potential with significant consequences on public health, including epidemic or pandemic potential OR possible significant threats to food safety	N
4	The disease has a significant impact on the economy of the Union, causing substantial costs, mainly related to its direct impact on the health and productivity of animals	N
5(a)	The disease has a significant impact on society, with in particular an impact on labour markets	N
5(b)	The disease has a significant impact on animal welfare, by causing suffering of large numbers of animals	NC
5(c)	The disease has a significant impact on the environment, due to the direct impact of the disease OR due to the measures taken to control it	N
5(d)	The disease has a significant impact on a long-term effect on biodiversity or the protection of endangered species or breeds, including the possible disappearance or long-term damage to those species or breeds	N

Colour code: green = consensus (Yes/No), yellow = no consensus (NC).

Table 5: Outcome of the expert judgement related to the criteria of section 2 of Annex IV (category B of Article 9) for Koi herpes virus disease (KHVD)

Criteria to be met by the disease: The disease needs to fulfil all of the following criteria		**Final outcome**
1	The disease is present in the whole OR part of the Union territory with an endemic character AND (at the same time) several Member States or zones of the Union are free of the disease	N
2.1	The disease is moderately to highly transmissible	NC
2.2	There be possibilities of airborne or waterborne or vector-borne spread	Y
2.3	The disease affects single or multiple species	Y
2.4	The disease may result in high morbidity with in general low mortality	NC
At least one criterion to be met by the disease: In addition to the criteria set out above at points 1–2.4, the disease needs to fulfil at least one of the following criteria		
3	The disease has a zoonotic potential with significant consequences on public health, including epidemic potential OR possible significant threats to food safety	N
4	The disease has a significant impact on the economy of the Union, causing substantial costs, mainly related to its direct impact on the health and productivity of animals	N
5(a)	The disease has a significant impact on society, with in particular an impact on labour markets	N
5(b)	The disease has a significant impact on animal welfare, by causing suffering of large numbers of animals	NC
5(c)	The disease has a significant impact on the environment, due to the direct impact of the disease OR due to the measures taken to control it	N
5(d)	The disease has a significant impact on a long-term effect on biodiversity or the protection of endangered species or breeds, including the possible disappearance or long-term damage to those species or breeds	N

Colour code: green = consensus (Yes/No), yellow = no consensus (NC).

Table 6: Outcome of the expert judgement related to the criteria of section 3 of Annex IV (category C of Article 9) for Koi herpes virus disease (KHVD)

Criteria to be met by the disease: The disease needs to fulfil all of the following criteria		**Final outcome**
1	The disease is present in the whole OR part of the Union territory with an endemic character OR in aquatic animals several Member States or zones of the Union are free of the disease	NC
2.1	The disease is moderately to highly transmissible	NC
2.2	The disease is transmitted mainly by direct or indirect transmission	Y
2.3	The disease affects single or multiple species	Y
2.4	The disease usually does not result in high morbidity and has negligible or no mortality AND often the most observed effect of the disease is production loss OR in aquatic animals the disease may result in high morbidity and usually low mortality AND often the most observed effect of the disease is production loss	NC

At least one criterion to be met by the disease: In addition to the criteria set out above at points 1–2.4, the disease needs to fulfil at least one of the following criteria		
3	The disease has a zoonotic potential with significant consequences on public health, or possible significant threats to food safety	N
4	The disease has a significant impact on the economy of parts of the Union, mainly related to its direct impact on certain types of animal production systems	Y
5(a)	The disease has a significant impact on society, with in particular an impact on labour markets	N
5(b)	The disease has a significant impact on animal welfare, by causing suffering of large numbers of animals	NC
5(c)	The disease has a significant impact on the environment, due to the direct impact of the disease OR due to the measures taken to control it	N
5(d)	The disease has a significant impact on a long-term effect on biodiversity or the protection of endangered species or breeds, including the possible disappearance or long-term damage to those species or breeds	N

Colour code: green = consensus (Yes/No), yellow = no consensus (NC).

Table 7: Outcome of the expert judgement related to the criteria of section 4 of Annex IV (category D of Article 9) for Koi herpes virus disease (KHVD)

Criteria to be met by the disease: The disease needs to fulfil all of the following criteria		**Final outcome**
D	The risk posed by the disease in question can be effectively and proportionately mitigated by measures concerning movements of animals and products in order to prevent or limit its occurrence and spread	NC
The disease fulfils criteria of section 1, 2, 3 or 5 of Annex IV of AHL		NC

Colour code: yellow = no consensus (NC).

Table 8: Outcome of the expert judgement related to the criteria of section 5 of Annex IV (category E of Article 9) for Koi herpes virus disease (KHVD)

Diseases in category E **need to fulfil criteria of Sections 1, 2 or 3 of Annex IV of AHL** and/or the following:		**Final outcome**
E	Surveillance of the disease is necessary for reasons relating to animal health, animal welfare, human health, the economy, society or the environment (If a disease fulfils the criteria as in Article 5, thus being eligible to be listed, consequently category E would apply.)	NC

Colour code: yellow = no consensus (NC).

3.3.1. Non-consensus questions

This section displays the assessment related to each criterion of Annex IV referring to the categories of Article 9 of the AHL where no consensus was achieved in form of tables (Tables 9–13). The proportion of Y, N or `na' answers are reported, followed by the list of different supporting views for each answer.

Table 9: Outcome of the expert judgement related to criterion 1 of Article 9

Question		**Final outcome**	**Response**		
			Y (%)	**N (%)**	**na (%)**
1 (cat.A)	The disease is not present in the territory of the Union OR present only in exceptional cases (irregular introductions) OR present in only in a very limited part of the territory of the Union	NC	10	90	0

Question		Final outcome	Response		
			Y (%)	N (%)	na (%)
1 (cat.C)	The disease is present in the whole OR part of the Union territory with an endemic character	NC	10	90	0
1 (cat.CAq)	In aquatic animals, several Member States or zones of the Union are free of the disease	NC	80	20	0

NC: non-consensus; number of judges: 10.

Reasoning supporting the judgement

Supporting Yes for 1 (cat.A):

- There is only irregular incursion.

Supporting Yes for 1 (cat.C):

- Most EU MSs are infected – only three of them are free and they have low fish production.

Supporting Yes for 1 (cat.CAq):

- According to the current distribution of endemic infected/ free countries at EU level, several MSs are free.
- There are only irregular incursions, leading to stamping out.

Table 10: Outcome of the expert judgement related to criterion 2.1 of Article 9

Question		Final outcome	Response		
			Y (%)	N (%)	na (%)
2.1 (cat.A)	The disease is highly transmissible	NC	70	30	0
2.1 (cat.B,C)	The disease is moderately to highly transmissible	NC	30	70	0

NC: non-consensus; number of judges: 10.

Reasoning supporting the judgement

Supporting Yes for 2.1 (cat.A):

- There is an observation of high mortality and high infection rates a few days after the introduction of the virus.

Supporting Yes for 2.1 (cat.B,C):

- Based on detection in most MSs but little impact reported despite longevity of the virus and lack of treatment availability, there is not always a high transmissibility.
- R_0 is unknown, so there is no clue that transmissibility is always high.

Table 11: Outcome of the expert judgement related to criterion 2.4 of Article 9

Question		Final outcome	Response		
			Y (%)	N (%)	na (%)
2.4 (cat.A)	The disease may result in high morbidity and significant mortality rates	NC	80	20	0
2.4 (cat.B)	The disease may result in high morbidity with in general low mortality	NC	10	90	0
2.4 (cat.CAq)	In aquatic animals, the disease may result in high morbidity and usually low mortality AND often the most observed effect of the disease is production loss	NC	10	90	0

NC: non-consensus; number of judges: 10.

Reasoning supporting the judgement

Supporting Yes for 2.4 (cat.A):

- Based on mortality estimated from field (10–20%) and experimental morbidity (100%).

Supporting Yes for 2.4 (cat.B):

- Based on the long-term position, even when an outbreak initially had high mortality. Fish that survive primary infection no longer show clinical signs. The best data available at present suggests fish exposed to the virus may remain infected for their lifetime.

Supporting Yes for 2.4 (cat.CAq):

- Morbidity is high, mortality is generally low, particularly when water temperatures are below 16°C, and only in the initial phase of the outbreak it can be high and even then it can be very variable. The disease leads to losses in the aquaculture production during an outbreak. Fish that survive primary infection no longer show clinical signs. In wild populations, KHV has been found in the brain of both seropositive and negative carp for over two years post outbreak. Serological testing of lakes that experienced clinical infections of KHV show that seropositive fish could be detected 9 years post-outbreak suggesting continued low level exposure to the virus and therefore persistence. The best data available at present suggests fish exposed to the virus may remain infected for their lifetime. In the UK, KHV has impacted carp fisheries (farms have largely been unaffected). Outbreaks occur on 10–24 fisheries per year, causing losses of upwards of 10% of carp. There was no information indicating that any fishery to date, in Europe, had ceased to trade because of KHV.

Table 12: Outcome of the expert judgement related to criterion 5(b) of Article 9

Question*		Final outcome	Response		
			Y (%)	N (%)	na (%)
5(b)	The disease has a significant impact on animal welfare, by causing suffering of large numbers of animals	NC	80	20	0

NC: non-consensus; number of judges: 10.
*At the time of the collective judgement the assessment of the current impact considering the control measures in place was considered.

Reasoning supporting the judgement

Supporting Yes:

- This is linked to high morbidity and mortality.

Supporting No:

- There may be high mortality with newly introduced infection, but apparently little thereafter despite continuing test positive detections.

Table 13: Outcome of the expert judgement related to criterion D of Article 9

Question		Final outcome	Response		
			Y (%)	N (%)	na (%)
D	The risk posed by the disease in question can be effectively and proportionately mitigated by measures concerning movements of animals and products in order to prevent or limit its occurrence and spread	NC	70	30	0

NC: non-consensus; number of judges: 10.

Reasoning supporting the judgement

Supporting Yes:

- The control relies on preventing the introduction and spread of the pathogen through a combination of good biosecurity, eradicating infected populations and applying movement restrictions to infected sites.
- Very little recurrence of disease has been observed at KHV positive sites suffering clinical outbreaks of KHV in the UK. However, the effectiveness of movement restrictions is complicated by the potential for latency of the virus in surviving stocks.

Supporting No:

- There are limited diagnostic tests available at EU level and they have a poor sensitivity. Silent spread of the virus through undetected infected animals not showing clinical signs is possible.
- Field experience shows that spread does occur in spite of control efforts.

3.3.2. Outcome of the assessment of criteria in Annex IV for Koi herpes virus (KHV) disease for the purpose of categorisation as in Article 9 of the AHL

As from the legal text of the AHL, a disease is considered fitting in a certain category (A, B, C, D or E corresponding to point (a) to point (e) of Article 9(1) of the AHL) if it is eligible to be listed for Union intervention as laid down in Article 5(3) and fulfils all criteria of the first set from 1 to 2.4 and at least one of the second set of criteria from 3 to 5(d) as shown in Tables 5–9. According to the assessment methodology (EFSA AHAW Panel, 2017), a criterion is considered fulfilled when the outcome is 'Yes'.

A description of the outcome of the assessment of criteria in Annex IV for KHV disease for the purpose of categorisation as in Article 9 of the AHL is presented in Table 14.

Table 14: Outcome of the assessment of criteria in Annex IV for KHV disease for the purpose of categorisation as in Article 9 of the AHL

Category	Article 9 criteria										
	1° set of criteria					2° set of criteria					
	1	2.1	2.2	2.3	2.4	3	4	5a	5b	5c	5d
	Geographical distribution	Transmissibility	Routes of transmission	Multiple species	Morbidity and mortality	Zoonotic potential	Impact on economy	Impact on society	Impact on animal welfare	Impact on environment	Impact on biodiversity
A	NC	NC	Y	Y	NC	N	N	N	NC	N	N
B	N	NC	Y	Y	NC	N	N	N	NC	N	N
C	NC	NC	Y	Y	NC	N	Y	N	NC	N	N
D	NC										
E	NC										

According to the assessment here performed, KHVD complies with the following criteria of the sections 1 to 5 of Annex IV of the AHL for the application of the disease prevention and control rules referred to in points (a) to (e) of Article 9(1):

1) To be assigned to category A, a disease needs to comply with all criteria of the first set (1, 2.1–2.4) and according to the assessment KHVD complies with criteria 2.2 and 2.3, whereas the assessment is inconclusive on compliance with criteria 1, 2.1 and 2.4. To be eligible for category A, a disease needs to comply additionally with one of the criteria of the second set (3, 4, 5a–d) and KHVD does not comply with criteria 3, 4, 5a, 5c and 5d, and the assessment is inconclusive on compliance with criterion 5b.
2) To be assigned to category B, a disease needs to comply with all criteria of the first set (1, 2.1–2.4) and according to the assessment KHVD complies with criteria 2.2 and 2.3, does not comply with criterion 1 and this assessment is inconclusive on compliance with criteria

2.1 and 2.4. To be eligible for category B, a disease needs to comply additionally with one of the criteria of the second set (3, 4, 5a–d) and KHVD does not comply with criteria 3, 4, 5a, 5c and 5d, and this assessment is inconclusive on compliance with criterion 5b.

3) To be assigned to category C, a disease needs to comply with all criteria of the first set (1, 2.1–2.4) and according to the assessment KHVD complies with criteria 2.2 and 2.3, whereas the assessment is inconclusive on compliance with criteria 1, 2.1 and 2.4. To be eligible for category C, a disease needs to comply additionally with one of the criteria of the second set (3, 4, 5a–d) and KHVD complies with criterion 4, does not comply with criteria 3, 5a, 5c and 5d, and this assessment is inconclusive on compliance with criterion 5b.
4) To be assigned to category D, a disease needs to comply with criteria of section 1, 2, 3 or 5 of Annex IV of the AHL and with the specific criterion D of section 4, whose assessment for KHVD is inconclusive.
5) To be assigned to category E, a disease needs to comply with criteria of section 1, 2 or 3 of Annex IV of the AHL and/or the surveillance of the disease is necessary for reasons relating to animal health, animal welfare, human health, the economy, society or the environment. The latter is applicable if a disease fulfils the criteria as in Article 5 and the assessment here performed for KHVD is inconclusive on compliance with the criteria as in Article 5.

3.4. Assessment of Article 8

This section presents the results of the assessment on the criteria of Article 8(3) of the AHL about KHVD. The Article 8(3) criteria are about animal species to be listed, as it reads below:

'3. Animal species or groups of animal species shall be added to this list if they are affected or if they pose a risk for the spread of a specific listed disease because:

a) they are susceptible for a specific listed disease or scientific evidence indicates that such susceptibility is likely; or
b) they are vector species or reservoirs for that disease, or scientific evidence indicates that such role is likely'.

For this reason, the assessment on Article 8 criteria is based on the evidence as extrapolated from the relevant criteria of Article 7, i.e. the ones related to susceptible and reservoir species or routes of transmission, which cover also possible role of biological or mechanical vectors.[6] According to the mapping, as presented in Table 5, section 3.2 of the scientific opinion on the ad hoc methodology (EFSA AHAW Panel, 2017), the main animal species to be listed for KHVD according to the criteria of Article 8(3) of the AHL are as displayed in Table 15.

[6] A vector is a living organism that transmits an infectious agent from an infected animal to a human or another animal. Vectors are frequently arthropods. Biological vectors may carry pathogens that can multiply within their bodies and be delivered to new hosts, usually by biting. In mechanical vectors the pathogens do not multiply within the vector, which usually remains infected for shorter time than in biological vectors.

Table 15: Animal species to be listed for Koi herpes virus disease (KHV) according to criteria of Article 8 (*source*: data reported in Section 3.1.1.1)

	Phylum	Class	Order	Family	Genus/Species
Susceptible	Chordata	Actinopterygii	Cypriniformes	Cyprinidae	*Cyprinus carpio* and its varieties, *Carassius auratus*, *Carassius carassius*
Reservoir	Mollusca	Bivalvia	Unionoida	Not specified	Not specified
	Arthropoda (subphylum: Crustacea)	Not specified	Not specified	Not specified	Not specified
	Chordata	Actinopterygii	Cypriniformes	Cyprinidae	*Carassius auratus*, *Ctenopharyngodon idella*, *Tinca tinca*, *Vimba* spp., *Abramis brama*, *Rutilus rutilus*, *Scardinius erythrophthalmus*, *Carassius gibelio*, *Hypophthalmichthys molitrix*, *Leuciscus idus*, Gobioninae
			Perciformes	Percidae	*Perca fluviatilis*, *Gymnocephalus cernua*
				Eleotridae	Not specified
				Microdesmidae (subfamily: Ptereleotrinae)	Not specified
			Esociformes	Esocidae	*Esox lucius*
			Siluriformes	Not specified	Not specified
			Acipenseriformes	Acipenseridae	*Acipenser gueldenstaedtii*, *Acipenser oxyrinchus*
Vectors	None				

4. Conclusions

TOR 1: *for each of those diseases an assessment, following the criteria laid down in Article 7 of the AHL, on its eligibility of being listed for Union intervention as laid down in Article 5(3) of the AHL;*

- According to the assessment here performed, it is inconclusive whether KHVD can be considered eligible to be listed for Union intervention as laid down in Article 5(3) of the AHL. Eligibility of listing KHVD is dependent on a decision on criterion 5 A(v).

TOR 2a: *for each of the diseases which was found eligible to be listed for Union intervention, an assessment of its compliance with each of the criteria in Annex IV to the AHL for the purpose of categorisation of diseases in accordance with Article 9 of the AHL;*

- According to the assessment here performed, since it is inconclusive whether KHVD can be considered to be listed for Union intervention as laid down in Article 5(3) of the AHL, then also the assessment of its compliance with each of the criteria in Annex IV to the AHL for the purpose of categorisation of diseases in accordance with Article 9 of the AHL is inconclusive.

TOR 2b: *for each of the diseases which was found eligible to be listed for Union intervention, a list of animal species that should be considered candidates for listing in accordance with Article 8 of the AHL.*

- According to the assessment here performed, since it is inconclusive whether KHVD can be considered to be listed for Union intervention as laid down in Article 5(3) of the AHL, then it is also inconclusive which animal species can be considered to be listed for KHV disease according to Article 8(3) of the AHL.

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Abbreviations

AHAW	EFSA Panel on Animal Health and Welfare
AHL	Animal Health Law
BIP	border inspection post
CFSPH	Center for Food Security and Public Health
CyHV-3	Cyprinid Herpes Virus-3
ELISA	enzyme-linked immunosorbent assay
IC2	internal control system
ICBA	Individual and Collective Behavioural Aggregation
IUCN	International Union for Conservation of Nature
KHV	Koi herpes virus
KHVD	Koi herpes virus disease
MS	Member State
OIE	World Organization for Animal Health
qPCR	quantitative PCR
ToR	Terms of Reference

Appendix A – Table of global occurrence of KHV according to the OIE WAHIS database

http://www.oie.int/wahis_2/public/wahid.php/Diseaseinformation/Diseasetimelines

Key to colours

There is no information available on this disease

Never reported

Disease absent

Disease suspected but not confirmed

Infection/infestation

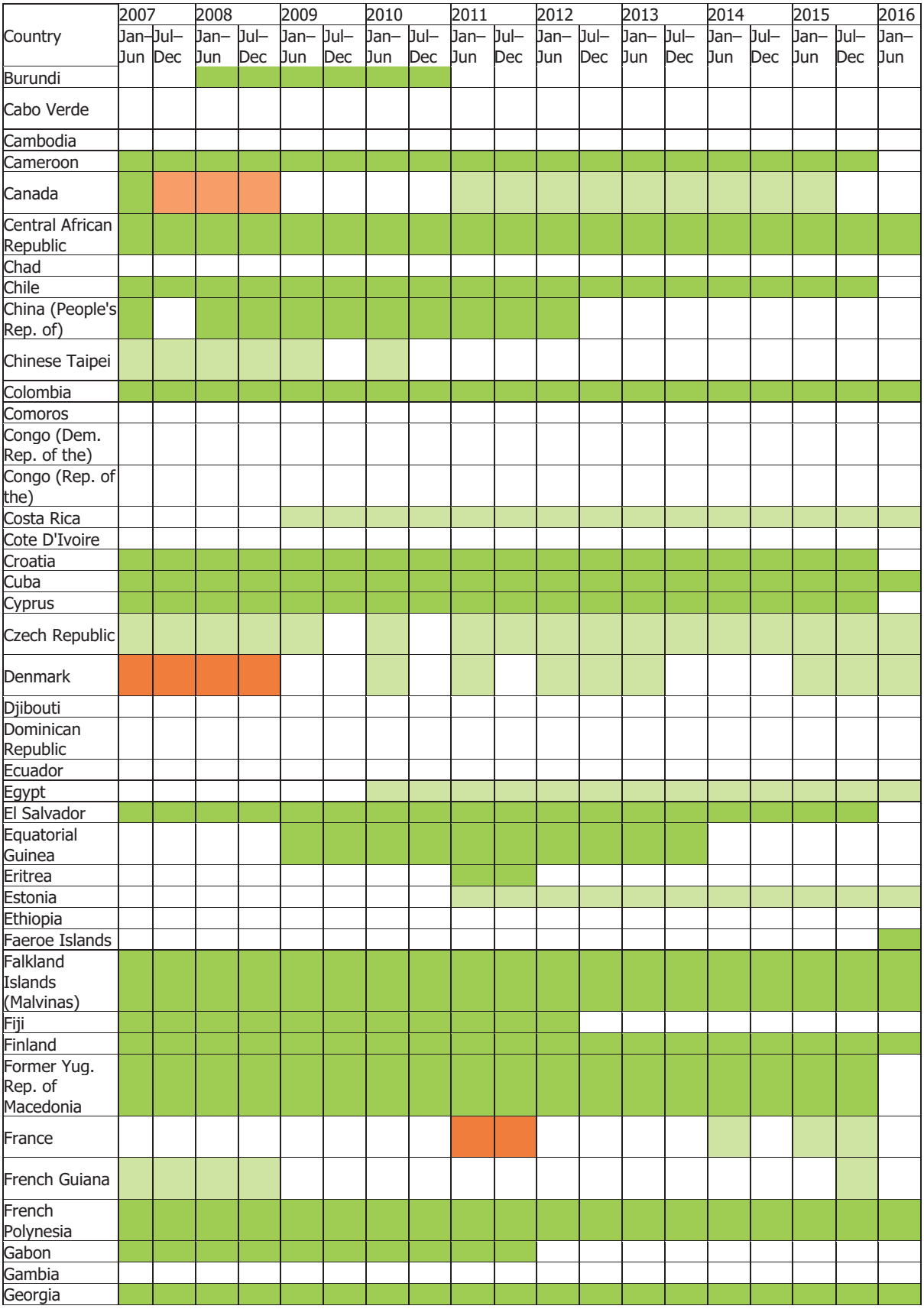
Disease present

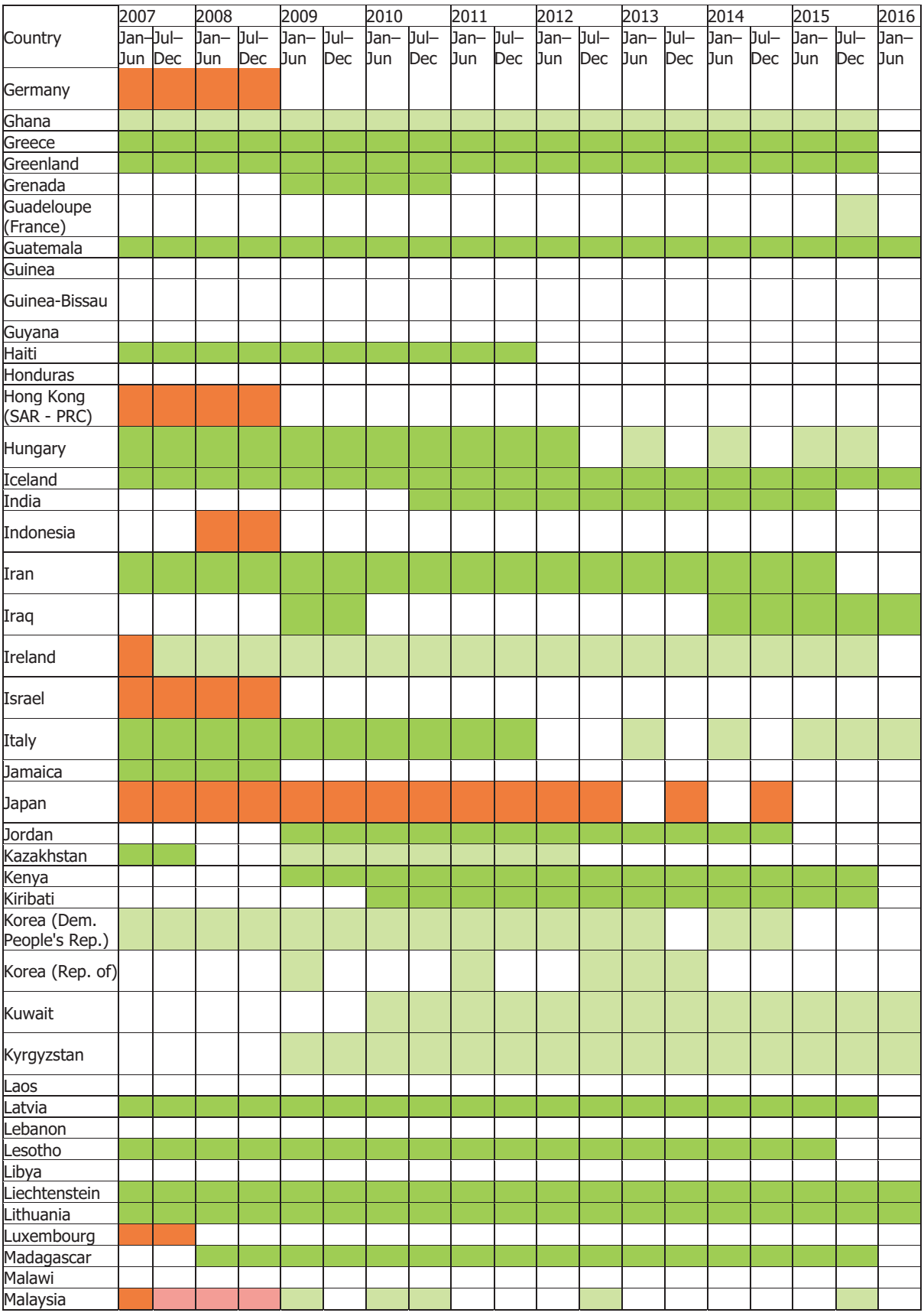
Disease limited to one or more zones

Infection/infestation limited to one or more zones

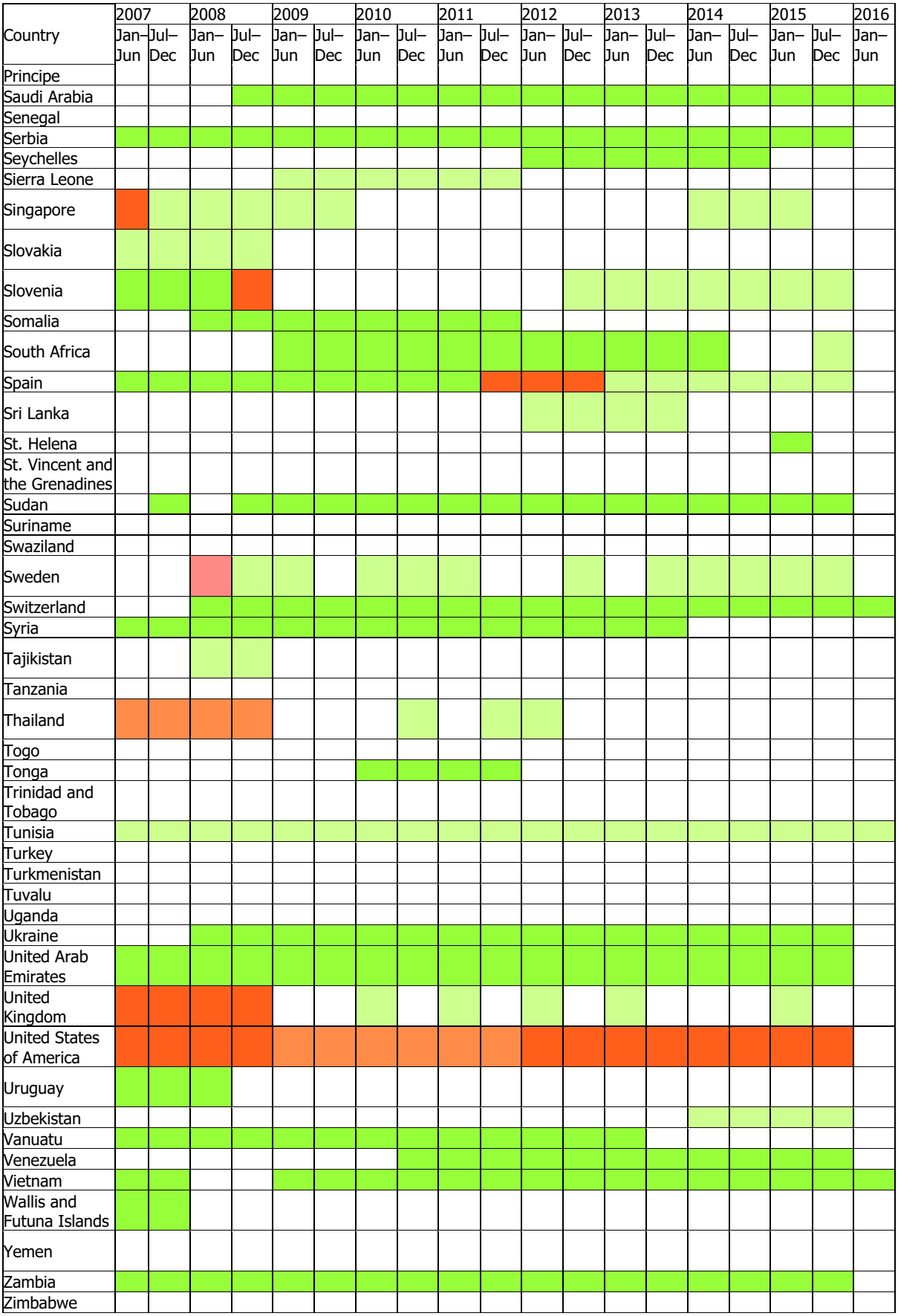
Disease suspected but not confirmed and limited to one or more zones

Country	2007		2008		2009		2010		2011		2012		2013		2014		2015		2016
	Jan–Jun	Jul–Dec	Jan–Jun	Jul–Dec	Jan–Jun	Jul–Dec	Jan–Jun	Jul–Dec	Jan–Jun	Jul–Dec	Jan–Jun	Jul–Dec	Jan–Jun	Jul–Dec	Jan–Jun	Jul–Dec	Jan–Jun	Jul–Dec	Jan–Jun
Afghanistan																			
Albania																			
Algeria																			
Andorra																			
Angola																			
Argentina																			
Armenia																			
Aruba																			
Australia																			
Austria																			
Azerbaijan																			
Bahrain																			
Bangladesh																			
Barbados																			
Belarus																			
Belgium																	N N		
Belize																			
Benin																			
Bhutan																			
Bolivia																			
Bosnia and Herzegovina																			
Botswana																			
Brazil																			
Brunei Darussalam																			
Bulgaria																			
Burkina Faso																			


Country
2007
2008
2009
2010
2011
2012
2013
2014
2015
2016
Jan–Jun
Jul–Dec
Burundi
Cabo Verde
Cambodia
Cameroon
Canada
Central African Republic
Chad
Chile
China (People's Rep. of)
Chinese Taipei
Colombia
Comoros
Congo (Dem. Rep. of the)
Congo (Rep. of the)
Costa Rica
Cote D'Ivoire
Croatia
Cuba
Cyprus
Czech Republic
Denmark
Djibouti
Dominican Republic
Ecuador
Egypt
El Salvador
Equatorial Guinea
Eritrea
Estonia
Ethiopia
Faeroe Islands
Falkland Islands (Malvinas)
Fiji
Finland
Former Yug. Rep. of Macedonia
France
French Guiana
French Polynesia
Gabon
Gambia
Georgia


Country
2007
2008
2009
2010
2011
2012
2013
2014
2015
2016
Jan–Jun
Jul–Dec
Germany
Ghana
Greece
Greenland
Grenada
Guadeloupe (France)
Guatemala
Guinea
Guinea-Bissau
Guyana
Haiti
Honduras
Hong Kong (SAR - PRC)
Hungary
Iceland
India
Indonesia
Iran
Iraq
Ireland
Israel
Italy
Jamaica
Japan
Jordan
Kazakhstan
Kenya
Kiribati
Korea (Dem. People's Rep.)
Korea (Rep. of)
Kuwait
Kyrgyzstan
Laos
Latvia
Lebanon
Lesotho
Libya
Liechtenstein
Lithuania
Luxembourg
Madagascar
Malawi
Malaysia

Country	2007		2008		2009		2010		2011		2012		2013		2014		2015		2016
	Jan–Jun	Jul–Dec	Jan–Jun	Jul–Dec	Jan–Jun	Jul–Dec	Jan–Jun	Jul–Dec	Jan–Jun	Jul–Dec	Jan–Jun	Jul–Dec	Jan–Jun	Jul–Dec	Jan–Jun	Jul–Dec	Jan–Jun	Jul–Dec	Jan–Jun
Maldives																			
Mali																			
Malta																			
Marshall Islands																			
Martinique (France)																			
Mauritania																			
Mauritius																			
Mayotte (France)																			
Mexico																			
Micronesia (Federated States)																			
Moldova																			
Mongolia																			
Montenegro																			
Morocco																			
Mozambique																			
Myanmar																			
Namibia																			
Nepal																			
Netherlands																			
New Caledonia																			
New Zealand																			
Nicaragua																			
Niger																			
Nigeria																			
Norway																			
Oman																			
Pakistan																			
Palau																			
Palestinian Auton. Territories																			
Panama																			
Papua New Guinea																			
Paraguay																			
Peru																			
Philippines																			
Poland																			
Portugal																			
Qatar																			
Reunion (France)																			
Romania																			
Russia																			
Rwanda																			
Samoa																			
San Marino																			
Sao Tome and																			


Country
2007
2008
2009
2010
2011
2012
2013
2014
2015
2016
Jan–Jun
Jul–Dec
Principe
Saudi Arabia
Senegal
Serbia
Seychelles
Sierra Leone
Singapore
Slovakia
Slovenia
Somalia
South Africa
Spain
Sri Lanka
St. Helena
St. Vincent and the Grenadines
Sudan
Suriname
Swaziland
Sweden
Switzerland
Syria
Tajikistan
Tanzania
Thailand
Togo
Tonga
Trinidad and Tobago
Tunisia
Turkey
Turkmenistan
Tuvalu
Uganda
Ukraine
United Arab Emirates
United Kingdom
United States of America
Uruguay
Uzbekistan
Vanuatu
Venezuela
Vietnam
Wallis and Futuna Islands
Yemen
Zambia
Zimbabwe